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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,	:	
	:	Civil Action No. 13-391-ES-SCM
Plaintiff/Counterclaim Defendant,	:	
	:	District Judge Esther Salas
v.	:	Magistrate Judge Steven C. Mannion
	:	
AMNEAL PHARMACEUTICALS, LLC,	:	
	:	
Defendant/Counterclaim Plaintiff.	:	
	x	

DEFENDANT AMNEAL PHARMACEUTICALS, LLC'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant-Counterclaim Plaintiff Amneal Pharmaceuticals, LLC ("Amneal") for its
Answer, Defenses, and Counterclaims to the Complaint of Plaintiff-Counterclaim Defendant
Jazz Pharmaceuticals, Inc. ("Jazz"), alleges as follows:

Nature of the Action

1. Admitted in part and denied in part. Amneal admits only that the Complaint purports to be a civil action alleging infringement of United States Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889 ("the '889 patent"), 7,262,219 ("the '219 patent"), 7,851,506 ("the '506 patent"), 7,895,059 ("the '059 patent"), 8,263,650 ("the '650 patent"), and 8,324,275 ("the '275 patent") (collectively, "patents-in-suit") in response to Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 203631 with the United States Food and Drug Administration ("FDA") for approval to market sodium oxybate oral solution 500 mg/mL. Amneal denies any remaining allegations or legal conclusions in Paragraph 1, and specifically denies that this action states a proper cause of action for patent infringement and denies that it has infringed, infringes, or will infringe any valid claim of the patents-in-suit.

The Parties

2. On information and belief, admitted.
3. Admitted.

Jurisdiction and Venue

4. Paragraph 4 contains conclusions of law to which no response is required. Amneal states that it will not contest subject-matter jurisdiction for purposes of this action only. To the extent any further response is required, Amneal denies any remaining allegations or legal conclusions in Paragraph 4.

5. For purposes of this action, Amneal consents to this Court's personal jurisdiction. Amneal denies all other allegations contained in paragraph 5 of the Complaint.

6. Paragraph 6 contains conclusions of law to which no response is required. Amneal will not contest venue for purposes of this action only. To the extent any further

response is required, Amneal denies any remaining allegations or legal conclusions in Paragraph 6.

The Patents-In-Suit

7. Admitted in part and denied in part. Amneal admits that the '431 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on October 29, 2002, and it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan as inventors. Amneal admits that a purported copy of the '431 patent is attached to the Complaint as Exhibit A. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 7, and on that basis denies those allegations. Amneal specifically denies that the '431 patent was duly and legally issued or that its claims are valid and enforceable.

8. Admitted in part and denied in part. Amneal admits that the '889 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on August 24, 2004, and it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan as inventors. Amneal admits that a purported copy of the '889 patent is attached to the Complaint as Exhibit B. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 8, and on that basis denies those allegations. Amneal specifically denies that the '889 patent was duly and legally issued or that its claims are valid and enforceable.

9. Admitted in part and denied in part. Amneal admits that the '219 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of

Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on August 28, 2007, and it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan as inventors. Amneal admits that a purported copy of the '219 patent is attached to the Complaint as Exhibit C. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 9, and on that basis denies those allegations. Amneal specifically denies that the '219 patent was duly and legally issued or that its claims are valid and enforceable.

10. Admitted in part and denied in part. Amneal admits that the '506 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on December 14, 2010, it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan as inventors, and it lists Jazz Pharmaceuticals, Inc. as the assignee. Amneal admits that a purported copy of the '506 patent is attached to the Complaint as Exhibit D. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 10, and on that basis denies those allegations. Amneal specifically denies that the '506 patent was duly and legally issued or that its claims are valid and enforceable.

11. Admitted in part and denied in part. Amneal admits that the '059 patent states on its face that it is titled "Sensitive Drug Distribution System and Method", that it issued on February 22, 2011, it lists Dayton T. Reardan, Patti A. Engle and Bob Gagne as inventors, and it lists Jazz Pharmaceuticals, Inc. as the assignee. Amneal admits that a purported copy of the '059 patent is attached to the Complaint as Exhibit E. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 11, and on

that basis denies those allegations. Amneal specifically denies that the '059 patent was duly and legally issued or that its claims are valid and enforceable.

12. Admitted in part and denied in part. Amneal admits that the '650 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on September 11, 2012, it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan as inventors, and it lists Jazz Pharmaceuticals, Inc. as the assignee. Amneal admits that a purported copy of the '650 patent is attached to the Complaint as Exhibit F. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 12, and on that basis denies those allegations. Amneal specifically denies that the '650 patent was duly and legally issued or that its claims are valid and enforceable.

13. Admitted in part and denied in part. Amneal admits that the '275 patent states on its face that it is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy", that it issued on December 4, 2012, it lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan as inventors, and it lists Jazz Pharmaceuticals, Inc. as the assignee. Amneal admits that a purported copy of the '275 patent is attached to the Complaint as Exhibit G. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 13, and on that basis denies those allegations. Amneal specifically denies that the '275 patent was duly and legally issued or that its claims are valid and enforceable.

The XYREM[®] Drug Product

14. Admitted in part and denied in part. Amneal admits that Jazz sells sodium oxybate oral solution under the registered trade name Xyrem[®]. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 14, and on that basis denies those allegations.

15. Admitted in part and denied in part. Amneal admits only that the '889, '219, '506, '059, '650, and '275 patents are listed in the FDA's Orange Book. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 15, and on that basis denies those allegations.

Acts Giving Rise to This Suit

16. Admitted in part and denied in part. Amneal admits that it filed ANDA No. 203631 ("Amneal's ANDA") with the FDA under § 505 of the Food, Drug, and Cosmetic Act ("FDCA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Amneal's ANDA Product"). Amneal denies the remaining allegations of Paragraph 16.

17. Admitted in part and denied in part. Amneal admits that Amneal's ANDA contained a written certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Amneal's Paragraph IV Certification") that the claims of the '889, '219, '506, '059, '650, and '275 patents are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product. Amneal admits that Amneal's Paragraph IV Certification also stated that the claims of U.S. Patent Nos. 7,668,730 ("the '730 patent"), 7,765,106 ("the '106 patent"), and 7,765,107 ("the '107 patent") are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product. Amneal denies the remaining allegations of Paragraph 17.

18. Admitted in part and denied in part. Amneal admits that on December 7, 2012 it sent written notice to Jazz ("Amneal's Notice Letter") that the claims of the '889, the '219, the '506, the '059, the '650, the '730, the '106, and the '107 patents are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product. Amneal admits that Amneal's Notice Letter states that Amneal seeks approval to engage in the commercial manufacture, use, and/or sale of 500 mg/mL sodium oxybate oral solution before the expiration of the '889, the '219, the '506, the '059, the '650, the '730, the '106, and the '107 patents. Amneal denies the remaining allegations of Paragraph 18.

Count I: Alleged Infringement of the '431 Patent

19. Amneal repeats and realleges its responses to Paragraphs 1-18 of the Complaint.

20. Admitted in part and denied in part. Amneal admits that it included a Paragraph IV Certification for the '889, '219, '506, '059, '650, '730, '106, and '107 patents to obtain approval to engage in the commercial manufacture, use, and/or sale of 500 mg/mL sodium oxybate. Amneal also admits that based on Jazz's filing of the Complaint, and Amneal's denial thereof, there is an actual, substantial, and continuing justiciable controversy between Amneal and Jazz having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding whether Amneal has infringed any valid enforceable claim of the '431 patent. Amneal denies the remaining allegations of Paragraph 20.

21. Denied.

22. Admitted.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Denied.

28. Denied.

Count II: Alleged Infringement of the '889 Patent

29. Amneal repeats and realleges its responses to Paragraphs 1-28 of the Complaint.

30. Denied.

31. Admitted.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

Count III: Alleged Infringement of the '219 Patent

38. Amneal repeats and realleges its responses to Paragraphs 1-37 of the Complaint.

39. Denied.

40. Admitted.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

Count IV: Alleged Infringement of the '506 Patent

- 47. Amneal repeats and realleges its responses to Paragraphs 1-46 of the Complaint.
- 48. Denied.
- 49. Admitted.
- 50. Denied.
- 51. Denied.
- 52. Denied.
- 53. Denied.
- 54. Denied.
- 55. Denied.

Count V: Alleged Infringement of the '059 Patent

- 56. Amneal repeats and realleges its responses to Paragraphs 1-55 of the Complaint.
- 57. Denied.
- 58. Admitted.
- 59. Denied.
- 60. Denied.
- 61. Denied.
- 62. Denied.
- 63. Denied.
- 64. Denied.

Count VI: Alleged Infringement of the '650 Patent

- 65. Amneal repeats and realleges its responses to Paragraphs 1-64 of the Complaint.
- 66. Denied.

67. Admitted.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

Count VII: Alleged Infringement of the '275 Patent

74. Amneal repeats and realleges its responses to Paragraphs 1-73 of the Complaint.

75. Denied.

76. Admitted.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

PRAYER FOR RELIEF

Amneal denies that Jazz is entitled to any judgment or relief against Amneal and, therefore, specifically denies paragraphs (A) through (K) of Jazz's Prayer for Relief.

AMNEAL'S DEFENSES

An allegation of any defense below is not an admission that Amneal bears the burden of proof or persuasion on any claim or issue.

First Defense – Noninfringement of the '431 Patent

83. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '431 patent, literally or under the Doctrine of Equivalents.

Second Defense – Invalidity of the '431 Patent

84. Upon information and belief, each claim of the '431 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Third Defense – Noninfringement of the '889 Patent

85. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '889 patent, literally or under the Doctrine of Equivalents.

Fourth Defense – Invalidity of the '889 Patent

86. Upon information and belief, each claim of the '889 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Fifth Defense – Noninfringement of the '219 Patent

87. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '219 patent, literally or under the Doctrine of Equivalents.

Sixth Defense – Invalidity of the '219 Patent

88. Upon information and belief, each claim of the '219 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Seventh Defense – Noninfringement of the '506 Patent

89. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '506 patent, literally or under the Doctrine of Equivalents.

Eighth Defense – Invalidity of the '506 Patent

90. Upon information and belief, each claim of the '506 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Ninth Defense – Noninfringement of the '059 Patent

91. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '059 patent, literally or under the Doctrine of Equivalents.

Tenth Defense – Invalidity of the '059 Patent

92. Upon information and belief, each claim of the '059 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Eleventh Defense – Noninfringement of the '650 Patent

93. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '650 patent, literally or under the Doctrine of Equivalents.

Twelfth Defense – Invalidity of the '650 Patent

94. Upon information and belief, each claim of the '650 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Thirteenth Defense – Noninfringement of the '275 Patent

95. Amneal's proposed product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '275 patent, literally or under the Doctrine of Equivalents.

Fourteenth Defense – Invalidity of the '275 Patent

96. Upon information and belief, each claim of the '275 patent is invalid for failure to comply with the conditions and requirements of the patent laws of the United States, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Fifteenth Defense – No Relief Available

97. Jazz is barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to §§ 286 and 287.

98. Jazz has not suffered any damages.

99. Jazz is not suffering an irreparable injury.

Sixteenth Defense – Failure to State a Claim

100. The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Reservation of Rights

101. Amneal reserves the right to assert such other defenses, including but not limited to defenses of unenforceability as well as defense(s) raised by another defendant in this action or any other action concerning the patents-in-suit, and damages that may appear as discovery proceeds in this case.

AMNEAL'S COUNTERCLAIMS

Counterclaim Plaintiff Amneal Pharmaceuticals, LLC ("Amneal"), for its counterclaims against Counterclaim Defendant Jazz Pharmaceuticals, Inc., ("Jazz"), allege as follows:

The Parties

1. Amneal is a limited liability company organized under the laws of Delaware having its principal place of business at 440 U.S. Highway 22 West, Suite 104, Bridgewater, New Jersey, 08807.

2. On information and belief, Counterclaim Defendant Jazz is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

Jurisdiction and Venue

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the United States Patent Laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).

4. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331 and 1338(a), 2201, and 2202, and 21 U.S.C. § 355(j)(5)(C).

5. Jazz has submitted to personal jurisdiction in this Court by suing Amneal, and previously Roxane Laboratories Inc. over the same patents, in this District. On information and belief, Jazz sells products here, including the Xyrem[®] product at issue in this case, and Jazz regularly conducts business in this District.

6. This Court is the proper venue under 28 U.S.C. §§ 1391, 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

7. This is an action for declaratory relief seeking a declaration of noninfringement and invalidity of U.S. Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889 ("the '889 patent"), 7,262,219 ("the '219 patent"), 7,851,506 ("the '506 patent"), 7,895,059 ("the '059 patent"), 8,263,650 ("the '650 patent"), 8,324,275 ("the '275 patent"), 7,668,730 ("the '730 patent"), 7,765,106 ("the '106 patent"), and 7,765,107 ("the '107 patent") (collectively, "the counterclaim patents").

Background

8. The face of the '431 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on October 29, 2002.

9. On information and belief, Jazz purports to be the owner of the '431 patent.

10. The face of the '889 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on August 24, 2004.

11. On information and belief, Jazz purports to be the owner of the '889 patent.

12. The face of the '219 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on August 28, 2007.

13. On information and belief, Jazz purports to be the owner of the '219 patent.

14. The face of the '506 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on December 14, 2010.

15. On information and belief, Jazz purports to be the owner of the '506 patent.

16. The face of the '059 patent, titled "Sensitive Drug Distribution System and Method," indicates that it issued on February 22, 2011.

17. On information and belief, Jazz purports to be the owner of the '059 patent.

18. The face of the '650 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on September 11, 2012.

19. On information and belief, Jazz purports to be the owner of the '650 patent.

20. The face of the '275 patent, titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," indicates that it issued on December 4, 2012.

21. On information and belief, Jazz purports to be the owner of the '275 patent.

22. The face of the '730 patent, titled "Sensitive Drug Distribution System and Method," indicates that it issued on February 23, 2010. A true and correct copy of the '730 patent as it issued is attached to this Answer as Exhibit 1.

23. On information and belief, Jazz purports to be the owner of the '730 patent.

24. The face of the '106 patent, titled "Sensitive Drug Distribution System and Method," indicates that it issued on July 27, 2010. A true and correct copy of the '106 patent as it issued is attached to this Answer as Exhibit 2.

25. On information and belief, Jazz purports to be the owner of the '106 patent.

26. The face of the '107 patent, titled "Sensitive Drug Distribution System and Method," indicates that it issued on July 27, 2010. A true and correct copy of the '107 patent as it issued is attached to this Answer as Exhibit 3.

27. On information and belief, Jazz purports to be the owner of the '107 patent.

28. Under 21 U.S.C. § 355(b)(1)(G) and 21 C.F.R. § 314.53, respectively, an NDA holder, here Jazz, must provide to the FDA the patent number and expiration date of any patent(s) that it believes "claims the drug for which the applicant submitted the application or which claims a method of using such drug" and "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

29. The FDA publishes patent(s) in an electronic, publicly available database called APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, also known as the "Orange Book." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are "purely ministerial." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

30. Amneal submitted ANDA No. 203631 ("Amneal's ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, and/or sale of 500 mg/mL sodium oxybate oral solution ("Amneal's ANDA Product").

31. Each of the counterclaim patents, except for the '431 patent, are listed in the FDA's Orange Book.

32. Amneal submitted ANDA No. 203631 to the FDA seeking permission to market the proposed 500 mg/mL sodium oxybate oral solution.

33. Amneal's ANDA contains a certification ("Amneal's Paragraph IV Certification") under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '889,'219,'506,'059,'650,'275,'730,'106, and '107 patents are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product.

34. Jazz filed its Complaint in this Court alleging that Amneal's act of submitting ANDA No. 203631 infringes the patents-in-suit.

35. Amneal denies that it infringes any valid and enforceable claim of the patents-in-suit, as well as the '730 patent, the '106 patent, and the '107 patent.

36. The present suit by Jazz impairs Amneal's ability to obtain approval of its ANDA No. 203821 and market the proposed sodium oxybate product described therein.

37. There remains a real and definite threat that Jazz may assert the '730, '106, and '107 patents against Amneal.

38. To the extent that any of the counterclaim patents, including the '730, '106, and/or '107 patents, forms the basis for a prior ANDA applicant's eligibility for 180-exclusivity under 21 USC 355(j)(5)(B)(iv), they will preclude the approval of Amneal's ANDA No. 203631 unless Amneal secures a final court decision of noninfringement, invalidity or unenforceability as to these patents.

39. Based on Jazz's filing of the Complaint, and Amneal's denial thereof, there is an actual, substantial, and continuing justiciable controversy between Amneal and Jazz having

adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding whether Amneal has infringed any valid and enforceable claim of the counterclaim patents.

40. Unless enjoined, Jazz will continue to assert that Amneal infringes the claims of the counterclaim patents, and Jazz is free to assert that Amneal infringes the claims of the '730,'106, and '107 patents. Amneal believes that this will continue to interfere with Amneal's business with respect to 500 mg/mL sodium oxybate oral solution.

41. Amneal will be irreparably harmed if Jazz is not enjoined from asserting the counterclaim patents against Amneal.

Count I

(Declaratory Judgment of Noninfringement)

42. Amneal repeats and realleges its responses in Paragraphs 1-41 of the Counterclaims as if fully set forth herein.

43. Amneal's proposed sodium oxybate product described in ANDA No. 203631 has not infringed, does not infringe, will not infringe, and will not contribute to or induce the infringement of any valid claim of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and/or '107 patents, either literally or under the doctrine of equivalents.

44. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that Amneal does not infringe the claims of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and/or '107 patents.

Count II

(Declaratory Judgment of Patent Invalidity)

45. Amneal repeats and realleges its responses in Paragraphs 1-45 of the Counterclaims as if fully set forth herein.

46. Each claim of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and '107 patents is invalid for failure to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112.

47. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the claims of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and/or '107 patents are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Amneal respectfully requests that this Court enter judgment in its favor and against Counterclaim Defendant Jazz and grant the following relief:

A. Dismiss Jazz's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. Declare that by filing ANDA No. 203631, Amneal has not infringed, is not infringing, and will not infringe, nor contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and '107 patents and that Amneal has a lawful right to obtain FDA approval of its ANDA No. 203631 for 500 mg/mL sodium oxybate oral solution;

C. Declare that the claims of the '431, '889, '219, '506, '059, '650, '275, '730, '106, and '107 patents are invalid;

D. Enjoin Jazz, its officers, employees, agents, representatives, attorneys and others acting on its behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Amneal, or charging them either verbally or in writing with infringement of any patent with respect to the sodium oxybate product described in ANDA No. 203631;

E. Declare that this is an exceptional case, and that Amneal be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285 based on, among other things, Jazz's lack of good faith in filing its Complaint;

F. Award costs and expenses to Amneal; and

G. Award Amneal such further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
*Attorneys for Defendant/Counterclaim
Plaintiff Amneal Pharmaceuticals, LLC*

Dated: April 15, 2013

By: s/ Paul H. Kochanski
Paul H. Kochanski
Tel: 908.654.5000
E-mail: pkochanski@ldlkm.com
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I hereby certify pursuant to Local Civil Rule 11.2, that to the best of my knowledge, information, and belief one or more of the patents at issue in this action are at issue in other actions.

1. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, case no. 10-6108 (D.N.J.) (Newark), before Judge Esther Salas. Plaintiff's complaint asserts United States Patent Nos. 6,780,889; 7,262,219; 7,668,730; 7,765,106; and 7,765,107.

2. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, case no. 11-0660 (D.N.J.) (Newark), before Judge Esther Salas. Plaintiff's complaint asserts United States Patent Nos. 6,472,431 and 7,851,506. This action was consolidated with case no. 10-6108 (D.N.J.) (Newark) on April 5, 2011.

3. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, case no. 11-2523 (D.N.J.) (Newark), before Judge Esther Salas. Plaintiff's complaint asserts United States Patent No. 7,895,059. This action was consolidated with case no. 10-6108 (D.N.J.) (Newark) on June 30, 2011.

4. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, case no. 12-6761 (D.N.J.) (Newark), before Judge Esther Salas. Plaintiff's complaint asserts United States Patent No. 8,263,650.

5. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, case no. 12-7459 (D.N.J.) (Newark), before Judge Esther Salas. Plaintiff's complaint asserts United States Patent No. 8,324,275.

Dated: April 15, 2013

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